PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: :

Yoko Hirakawa, et al. : Group Art Unit: 1643

Appln. No.: 10/530,171 : Examiner: BRISTOL, LYNN ANNE

Filed: May 17, 2005 :

For: ANTIBODY RECOGNIZING ANTIGEN

DECLARATION UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patent
Alexandria, VA 22313-1450

Sir:

Now comes Yoko Hirakawa who declares and states:

1. That I received a Master's degree from The University of Tokyo, Graduate School of Pharmaceutical Sciences, Department of Medical Pharmaceutics in the year 1986.

2. That I was employed by Mitsubishi Kasei Corporation (present Mitsubishi Chemical Corporation) in the year 1986, transferred from that company to Mitsubishi-Tokyo Pharmaceuticals, Inc. (next name; Mitsubishi Pharma Corporation, then present name; Mitsubishi Tanabe Pharma Corporation) in the year 2007, and have been engaged in research and development of cancer antibody at the Advanced Medical Research of Mitsubishi Tanabe Pharma Corporation.

3. That understand the English language or, at least, that the content of the Declaration were made clear to me prior to executing the same.

4. That the following experiment was carried out by me or under my direct supervision and control.

5. That my name was incorrectly indicated in the originally filed Oath and Declaration for the above-identified application. The U.S. Patent and Trademark Office is being notified of the correct spelling of my name, Yoko Hirakawa, with the submission of a Supplemental Application Data Sheet submitted concurrently herewith.

EXPERIMENTATION

(1) According to the method described in "Reactivity comparison of GAH antibody by flow cytometry" in Example 1 of the present specification, the reactivity of the GAH antibody with the cells forming a tumor mass was measured.

The results obtained are shown in Fig. A, and the results correspond to the raw data in Fig. 1 of the present specification.

The data supports that the present invention is intended that every cell in the solid tumor mass would express part of the non-muscle myosin heavy chain A (nmMHC-A) antigen (SEQ ID NO: 17) on its cell surface.

(2) According to the method described in "Immuno-staining of nude mouse transplantation cancer cell sections using nmMHCA-expressing cell lines" in Example 2 of the present specification, the reactivity of the GAH antibody or the anti-nmMHCA antibody (the anti-nmMHCA antibody obtained by

immunizing the peptide represented by SEQ ID NO: 22 of the present application) with the cells derived from colon cancer, the cells derived from esophageal cancer, or the cells derived from breast cancer, respectively, was measured.

The results obtained are shown in Fig. B (the reactivity of the GAH antibody or the anti-nmMHCA antibody with the cells derived from colon cancer or the cells derived from esophageal cancer, respectively) and Fig. C (the reactivity of the GAH antibody or the anti-nmMHCA antibody with the cells derived from breast cancer, respectively).

The data can be ground that "a cell" described in the present claims 1, 3, and 4 is limited to a cell derived from gastric cancer, a cell derived from breast cancer, a cell derived from colon cancer, or a cell derived from esophageal cancer.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectively submitted,

Date: 11/9/2007

Yoko Hirakawa

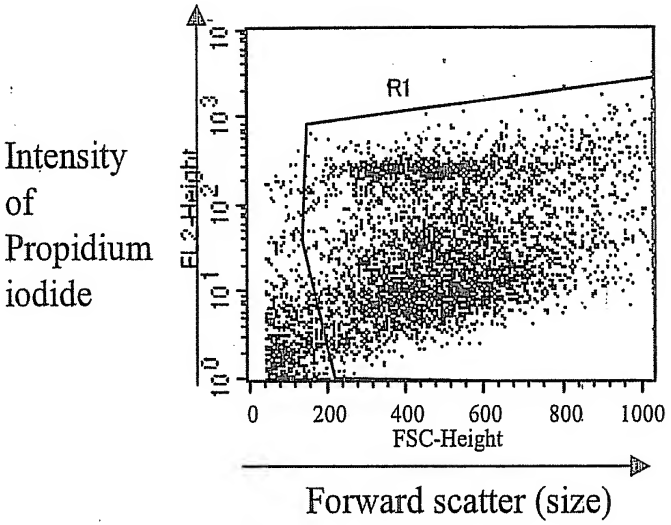
Yoko Hirakawa

Attachemts: Figs. A, B, and C

Fig. A

Tumor cells formed by subcutaneous transplantation of MKN45 were allowed to react with the FITC-labeled GAH and normal human IgG. Cell debris were removed (R1) and the reactivity of GAH and normal human IgG were compared.

The resuls shows that GAH reacts to all populations of the tumor cells.



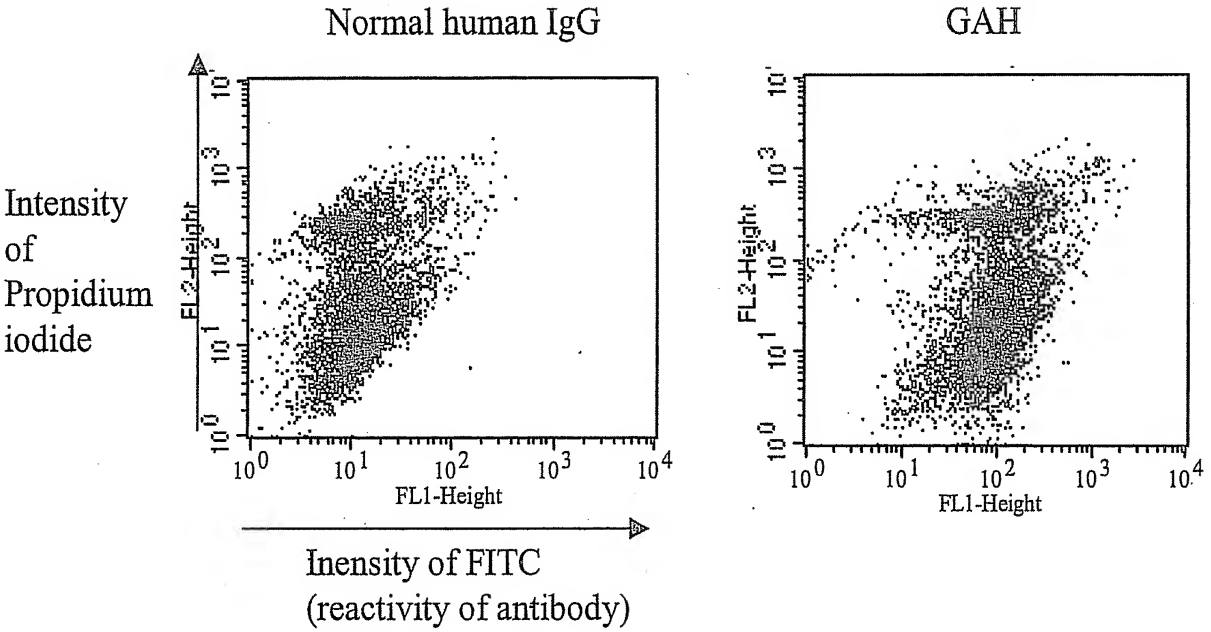


Fig. B

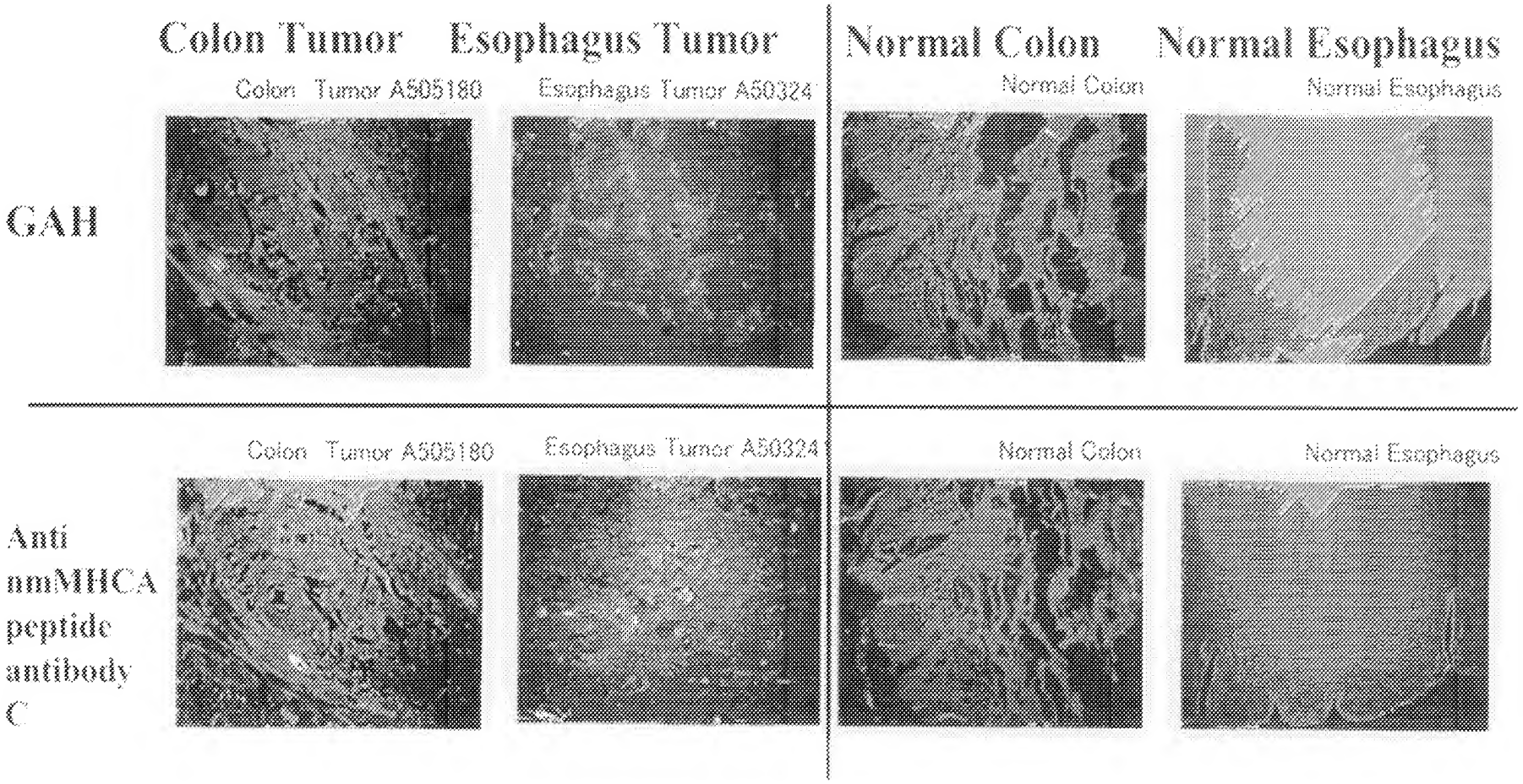
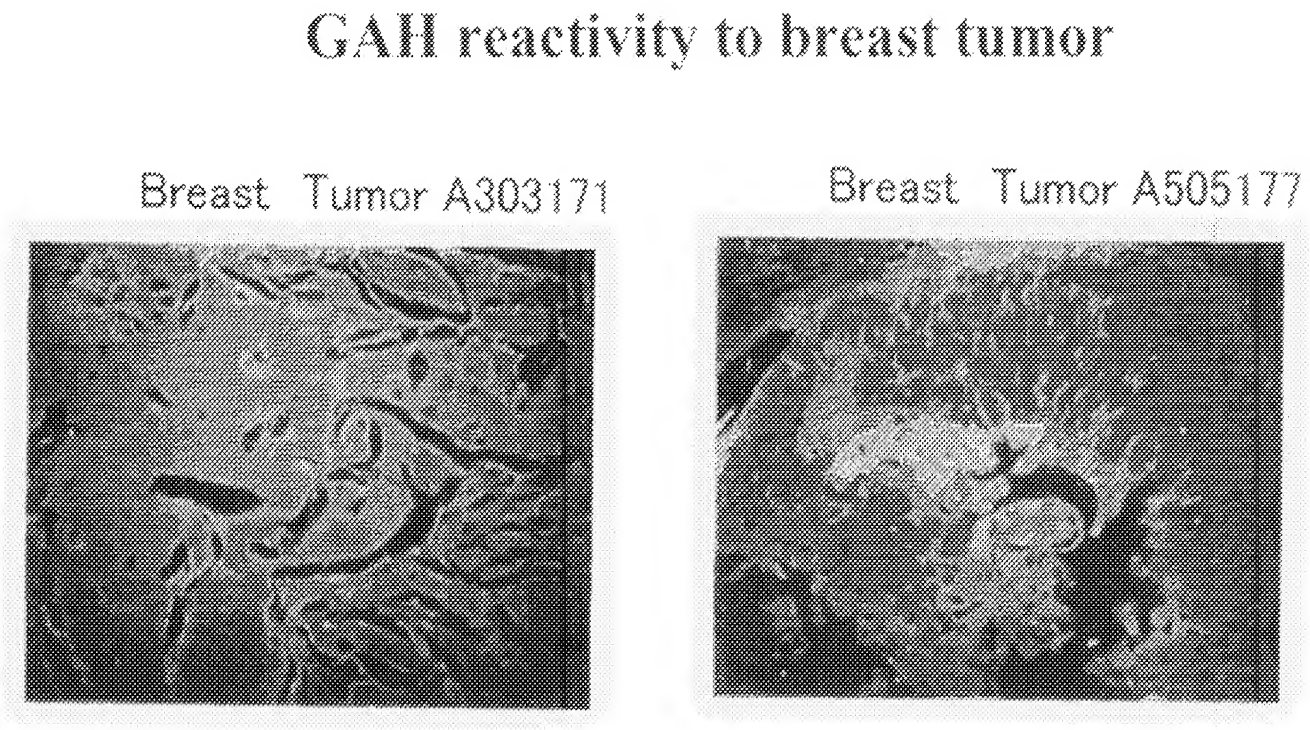

Colon Tumor
Esophagus Tumor
Normal Colon
Normal Esophagus
Colon Tumor A505180
Esophagus Tumor A50324
Normal Colon
Normal Esophagus
GAH
Colon Tumor A505180
Esophagus Tumor A50324
Normal Colon
Normal Esophagus
Anti nmMHCA peptide antibody C

Fig. C


GAH reactivity to breast tumor
Breast Tumor A303171
Breast Tumor A505177